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## Discussion

**Dr Rakesh M. Suri** *(Rochester, Minn)*. I would like to thank the Association for the privilege of discussing this paper. By way of disclosure, I am the principal investigator for the FDA IDE trial of the Sorin PERCEVAL valve, but I have no disclosures related to this discussion. I would like to thank Dr Bonaros for sending me a copy of his manuscript in advance.

Dr Bonaros and his colleagues present a study aiming to evaluate the impact of paravalvular leakage, PVL, on hemodynamics and outcome using the relative amplitude index. The authors used ROC analysis to determine that a cut-off point of 14 was associated with increased perioperative respiratory failure, acute renal injury, mortality, and cardiac and renal complications. Interestingly, however, amplitude index and PVL were both found to be independent predictors of mortality at one year.

This is an innovative attempt at developing a simplified hemodynamic parameter to ascertain the degree of periprosthetic regurgitation after TAVR. We recall the recently published Sinning aortic regurgitation index that Dr Bonaros has alluded to today, calculated according to the formula he also described.

That study, too, utilized ROC analysis delineating an index of less than 25 as important in predicting increased one-year mortality compared with those with an index of greater than 25. The Sinning index also provided additional prognostic information beyond echocardiographically assessed severity of PVL.

Now, both of these mathematical formulae are so-called simple bedside assessments of PVL and may potentially facilitate decisions regarding the need for further balloon dilation of the prosthesis or perhaps TAVR-in-TAVR procedures to ameliorate periprosthetic leak in the operating room.

However, the numbers are small in both studies, so we are mindful of the fact that this may limit the statistical robustness of the proposed relationship between the relative amplitude index (RAI) and the aforementioned end points.

Three simple questions, Dr Bonaros. The first, you alluded to this briefly, but can you please describe what you feel is the true benefit of this new index versus the Sinning index?

Second, the audience would benefit from a description of how your method might be influenced by alterations in ventricular load, and particularly, how it might be affected by either a hypertrophied ventricle that is poorly compliant and less likely to tolerate acute aortic insufficiency versus one preconditioned by the preoperative volume overload associated with significant preexistent regurgitation.

And, finally, could Dr Bonaros postulate why the RAI and PVL in the current analysis were independent predictors of death considering they are presumably related.

I would like to congratulate Dr Bonaros for an excellent presentation and thank the Association for the privilege of discussing this important work.

**Dr Bonaros.** Thank you, Dr Suri, for the excellent remarks. Just brief answers to your questions.

Number one, the differences between the Sinning index and our index; I think that both series have a series sample of a little bit more than 100 patients. I think the Bonow group had 140 patients. We had 110.

PM

The difference is that we just use simple blood pressure measurements. This is a decision you reballoon this valve or even to do a valve-in-valve. But, of course, it is a decision whereby you can adjust your medical therapy for those patients to reduce the afterload after the procedure on the ward or even ambulatory. This is the first thing. And, of course, you don't need any invasive measurement with a catheter in the left ventricle or even echocardiography.

For your second question, I agree with you that there is a very huge difference if the patients had preexisting regurgitation or this regurgitation happens acutely. So patients with preexisting regurgitation, in other words with a pure aortic stenosis, who do then have periprosthetic regurgitation, they would probably have an impaired outcome. This is the major hypothesis of this study.

There was a very good article two years ago in *American Heart Journal* entitled "Paravalvular Leakage from Pressure Overload to Volume Overload." So in this case, we have a volume overload in the left ventricle, and this ventricle is not able to compensate for this overload. So there should be some truth in this postulation.

For your third question, we were also surprised to see that both the index and the paravalvular regurgitation were independent predictors. I, frankly, do not know the answer to the question. I can only hypothesize that by using the frame of the valve in the aortic annulus, we change the geometry of the annulus, and of course we change the compliance of the aortic root. So probably some part of this so-called windkessel function of the aortic root is not available anymore.

So probably there should be some correlation there, too, and the question is what happens? What is the difference between the two valve groups we have available for TAVI if a balloon-expandable valve reacts in a different way than a self-expandable valve.

**Dr Lyle D. Joyce** *(Rochester, Minn).* Are you using this to change your practice as yet?

**Dr Bonaros.** To be honest, we have now started to take it into consideration because we have now finished the evaluation. Again, the numbers are limited. But we have started to take it into consideration. The example I brought was the last patient we did last week. We did take the RAI into consideration, yes.

**Dr Joyce.** Great. Thank you. Very nice presentation.

**Dr Joseph J. Rubelowsky** *(Hattiesburg, Miss).* When you calculated your index, you got a preoperative value, and you subtracted it from your postoperative value. Was there any preoperative regurgitation, and would that influence what your index would be as your final result?

Let's say if you had aortic stenosis with a one- or two-plus aortic regurgitation to begin with, and then you ended up with no aortic stenosis and maybe one-plus paravalvular leak, would that influence what your index would be, I mean, when you predicted at the end?

**Dr Bonaros.** You are absolutely right. So if you have preexisting regurgitation, the subtrahend of the formula, is going to be high.

So if the patient had a preexisting regurgitation grade 3 and ends up a grade 2, he has an improved index. You are absolutely right. But, fortunately, it was just two patients, so this would not affect our results. That is a good point.